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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,362	07/07/2003	Christopher J. M. Meade	1/1363	7889

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,362	MEADE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 34-37* is/are pending in the application.

4a) Of the above claim(s) *9-31 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Reply filed February 2, 2007 is acknowledged. Claims 32 and 33 are canceled. Claims 1-31 and 34-37 remain under consideration. Claims 1-8 and 35-37, drawn to pharmaceutical compositions, kits and therapeutic methods, remain under consideration. Claims 9-31 and 34, drawn to non-elected subject matter, remain withdrawn from consideration, 37 CFR 1.142(b).

Applicants' arguments have been fully considered and are persuasive in part. Rejections or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant claims.

Claims 1-8 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Neurokinin receptor antagonists are identified as NK_1, NK_2 and NK_3. Some antagonists may exhibit dual activity. The present claims are limited to **NK_1** antagonists. However, not all species recited in claim 4 are NK_1 antagonists. The specie MEN-11420 is an NK_2 antagonist. As such, Applicants have failed to define the invention properly. A review as to the receptor selectivity of the recited species is suggested.

Further, Applicants have employed two distinct types of nomenclature to depict those NK_1 receptor antagonists contemplated. For uniformity, each compound should be recited by the name that is most readily recognized, as, for example, N-[2-(3,5-bis-

trifluoromethylphenyl)ethyl]-2-{4-[(3-hydroxypropyl)methylamino]piperidin-1-yl}-N-methyl-2-phenylacetamide.

Claims 4 and 5 contain the trade names BIIF 1149, CP-122721, FK-888, NKP 608C,NKP 608A, CGP 60829, SR 140333, LY 303 870, MEN- 11420, SB 223412, MDL- 105172A, MDL- 103896, MEN-11149, MEN-11467, DNK 333A, SR-144190, YM-49244, YM-44778, ZM 274773, MEN-10930, S-19752, YM-35375, DA-5018, MK-869, L-754030, C J- 11974, L-758298, DNK-33A, 6b-I, C J- 11974, TAK-637 and GR 205171. Where a trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App.1982). The claim scope is uncertain since the trade name cannot always be used properly to identify any particular material. A trade name is used to identify a source of goods, and not the goods themselves. Thus, a trade name does not identify or describe the goods associated with the trade name. In the present case, a research designation is used to identify the species that are alleged to be NK_1 receptor antagonists and, accordingly, the identification/description is indefinite.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of Meissner et al., U.S. Patent No. 6,706,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because when A forms an epoxy group, R^1, R^2 and R^7 are methyl and the other R groups are hydrogen, the anticholinergic is the compound of instant formula 1 that is combined with an antiallergic agent to treat asthma or COPD. The composition claim of the patent comprise anti-allergic agents, i.e., compounds that relieve allergies, conditions characterized by abnormally high acquired sensitivity to substances such as drugs, pollen or microorganisms. Leroy et al., Expert Opinion on Investigational Drugs, cited for evidentiary purposes only, teaches the role of neurokinin in the pathology of allergic asthma. See pages 741-742, section 3.2.1. The NK_1 antagonists FK-888 and SR-140,333 are disclosed to be effective in the treatment of bronchoconstriction of allergic asthma.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meissner et al., U.S. Patent No. 6,706,726, and Leroy et al., Expert Opinion on Investigational Drugs.

Meissner teaches the administration of anticholinergic compounds of formula I wherein A forms an epoxy group, X^- is an anion, such as chloride, bromide, or methanesulphonate, R^1, R^2 and R^7 are methyl and the other R groups are hydrogen, that may be combined with an anti-allergic agent to treat asthma or COPD. See column 20, lines 14-15. Anti-allergic agents are compounds that relieve allergies, conditions characterized by abnormally high acquired sensitivity to substances such as drugs, pollen or microorganisms. As required by claims 35 and 37, see column 19, lines 60-65, where treatment of chronic obstructive pulmonary disease and asthma is disclosed. Leroy et al., Expert Opinion on Investigational Drugs, teaches the role of neurokinin in the pathology of allergic asthma. See pages 741-742, section 3.2.1. The NK_1 antagonists FK-888 and SR-140,333 are disclosed to be effective in the treatment of bronchoconstriction of allergic asthma.

In view of the combined teachings of the cited prior art, the skilled artisan in pulmonology would have been motivated to combine an anticholinergic compound of formula I and an NK_1 antagonist, such as FK-888 and SR-140,333, for example, with a reasonable expectation of successfully treating a disease of the respiratory tract, such as asthma or chronic obstructive pulmonary disease. It is generally *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but rather what they would collectively suggest to one of ordinary skill in the art. *In re Burckel*, 201 USPQ 67 (CCPA).

With respect to the selection of a specific NK_1 antagonist, optimal proportions of the ingredients in the claimed compositions and an optimal dosage of the active agents in the instant compositions, it is not inventive to discover the optimum or workable ranges or preferred embodiments by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Packaging in the form of a kit is conventional practice.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

April 13, 2007

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER